

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

Filed: April 8, 2024

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DAVID MCBANE, *on behalf of R.M.*, \*

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Petitioner, \*

No. 19-350V

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v. \*

Special Master Gowen

\*

SECRETARY OF HEALTH \*

AND HUMAN SERVICES, \*

\*

Respondent. \*

\* \* \* \* \*

*Mark T. Sadaka*, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for petitioner.

*Meghan Murphy*, U.S. Dept. of Justice, Washington, D.C., for respondent.

### **DISMISSAL DECISION<sup>1</sup>**

On March 7, 2019, David McBane, on behalf of R.M. (“petitioner”), filed a petition for compensation in the National Vaccine Injury Compensation Program.<sup>2</sup> Petition (ECF No. 1). Petitioner alleged that as a result of R.M. receiving the diphtheria-tetanus-acellular pertussis, inactivated polio vaccine (“Kinrix”) and the measles-mumps-rubella (“MMR”) and varicella (“ProQuad”) vaccine on March 9, 2019, he developed transverse myelitis. *Id.* After a review of the evidence filed in this matter, I find that petitioner has not established that he is entitled to compensation, and therefore, the petition shall be dismissed.

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<sup>1</sup> Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court’s website is at <http://www.uscfc.uscourts.gov/aggregator/sources/7>. Before the opinion is posted on the Court’s website, each party has 14 days to file a motion requesting redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court’s website without any changes.** *Id.*

<sup>2</sup> The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter “Vaccine Act” or “the Act”). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

## I. Procedural History

To accompany the petition, petitioner filed medical records to support his claim. *See* Pet'r Exs. 1-11. After a review of the medical records, respondent file the Rule 4(c) report, recommending against compensation. Resp. Report ("Rept.") (ECF No. 31). In the Rule 4(c) report, respondent did not deny that R.M. suffered from transverse myelitis, however, respondent asserted that petitioner failed to provide any evidence to satisfy any of the *Althen* prongs, and therefore, compensation should be denied. *Id.* at 5-8.

In response, petitioner filed an expert report from Alberto Martinez-Arizala, M.D., a neurologist. Pet'r Ex. 16 (ECF No. 46). Petitioner also filed medical literature to accompany Dr. Martinez-Arizala's report. Pet'r Exs. 18-25 (ECF No. 47). Respondent filed an expert report from Timothy E. Lotze, M.D. Resp. Ex. A (ECF No. 50).

The undersigned held a status conference on October 17, 2023. Rule 5 Order (ECF No. 52). During the status conference, I explained that the onset of R.M.'s transverse myelitis, occurring approximately 67 or 68 days after the administration of the vaccines he received on March 9, 2016, makes it difficult to prove *Althen* prong three. *Id.* at 2. Petitioner's counsel was given thirty days to file additional evidence to demonstrate that R.M.'s symptoms began closer in time to vaccine administration.

On November 20, 2023, petitioner filed a status report requesting additional time to file additional evidence to support onset and I granted petitioner an additional thirty days to file supporting evidence. Pet'r Status Rept. (ECF No. 53). On December 21, 2023, petitioner again requested an additional sixty days to file additional evidence to support onset and to show an appropriate temporal relationship between the vaccine and the onset of R.M.'s symptoms. Pet'r Status Rept. (ECF No. 55). After failing to file additional evidence by February 20, 2024, petitioner filed a motion for an extension of time to March 20, 2024 to file additional evidence supporting an appropriate timeframe between vaccine administration and onset of R.M.'s symptoms. Pet'r Motion for Extension of Time (ECF No. 56). In the motion for an extension of time, counsel stated that he had been unable to speak to petitioner or his family regarding additional evidence and requested an additional thirty days to file additional evidence regarding onset. *Id.* at 1.

In response to petitioner's motion, observing that it had been 92 days since petitioner was first ordered to file additional evidence supporting onset to show an appropriate temporal relationship between the vaccine and the beginning of R.M.'s condition, I issued an Order to Show Cause. Order to Show Cause (ECF No. 57). The Order to Show Cause again gave petitioner an additional thirty days, until March 25, 2024 to file evidence to support an appropriate temporal relationship between the vaccine and R.M.'s condition. *Id.*

Petitioner filed a supplemental expert report from Dr. Martinez-Arizala and four additional medical articles in response to the Order to Show Cause. Pet'r Exs. 43-47 (ECF No. 58). Additionally, petitioner filed a response to the Order to Show Cause, stating that counsel

called petitioner and his wife 12 times, mailed them copies of the Rule 5 Order and the Order to Show Cause, and sent six e-mails indicating that additional evidence was needed or the case would be dismissed. Pet'r Response to Order to Show Cause (ECF No. 59). The response acknowledges that no additional evidence has been provided, but that there is sufficient evidence filed by petitioner to make a ruling based on the evidence filed to-date. *Id.* at 3.

Accordingly, this matter is now ripe for adjudication.

## **II. Relevant evidence**

### **a. Medical records**

R.M. received the DTaP-IPV and MMR vaccines on March 9, 2016. Pet'r Ex. 1 at 49-50. The first medical record after R.M.'s vaccination was on May 16, 2016, when he was taken to the emergency department of St. Vincent Medical Center for an evaluation of leg pain and being unable to put weight on his left leg. Pet'r Ex. 3 at 2. R.M. was discharged from the emergency room, but a note indicated that "it was difficult to perform a formal neurologic exam because [R.M.] was so sleepy." *Id.* The following day, on March 17, 2016, R.M. was taken to Oregon Health & Science University where he was initially discharged after R.M.'s abdominal pain had resolved. Pet'r Ex. 2 at 145. However, R.M.'s mother returned almost immediately to the ER, stating that R.M. vomited again in the car and stating that he could not feel his feet. *Id.* Dr. Robert Cloutier wrote:

Patient refused to stand and appeared to have flaccid paralysis below the hips. Upon further interview, I learned the last time the mother had actually seen the patient walking was approximately 6:30 yesterday evening. The mother denies any trauma and denies any evidence of unsteady gait or ataxia prior to 6:30....Following my exam, I noted patient was completely insensate at the level of approximately T12. Patient is areflexic with no deep tendon reflexes at the level of the patella or Achilles....An emergent MRI was arranged of the total spine with a differential diagnosis to include transverse myelitis versus Guillain-Barré syndrome versus ADEM.

Pet'r Ex. 2 at 145. R.M. was then admitted to the hospital for additional care. R.M. had a spinal MRI which revealed a "long segment of smooth moderate cord expansion from the level of T9 to the conus with extensive T2 hyper intensity, more intense in the central portion of the cord. Findings most likely represent transverse myelitis." *Id.* at 28. The pediatric neurology consult note written by Dr. Allison Empey on May 17, 2016 stated:

[R.M.] is a 4-year 3 month previously healthy male with acute onset lower extremity paraplegia. Was in his usual state of health until Monday evening. Mom walked with [R.M.] to get a slurpee at 7-11 around 6:30 pm. He was walking fine. Went home and he was laying on mom's bed playing with her phone. She took her phone away to answer the phone and he started whining and slid off the bed....Mom picked him up and put him back on the bed...She then left the room and then when went back into the room he was on the floor again. She did not see if he fell or if he tried to walk and fell. Seemed to

be clutching at his lower abdomen/suprapubic area. When he was crying for 30 minutes, mom took him to ED at St. Vincent. While he was there he complained of abdominal pain. Was discharged. However, worsening pain so returned to DCH ED. Was evaluated for abdominal pain, but when [R.M.]...stood up to be discharged noted to have paralysis.

Pet'r Ex. 2 at 26. R.M. was treated with high dose steroids for 5 days. *Id.* R.M. was discharged on May 26, 2016, however, he was unable to use his lower limbs and had absent sensation from T5-6 and below. A note from R.M.'s record notes that the last time he was seen walking was on Monday, May 16, 2016. *See* Pet'r Ex. 2 at 145 ("Upon further interview, I learned the last time the mother had actually seen the patient walking was approximately 6:30 pm yesterday evening. The mother denies any trauma and denies any evidence of unsteady gait or ataxia prior to 6:30 pm.").

R.M. was admitted to inpatient rehabilitation center from May 26, 2016 through June 3, 2016. Pet'r Ex. 4 at 41-53. On September 1, 2016, R.M. had a follow-up appointment at the Oregon Health and Science University Neurology Clinic. Pet'r Ex. 2 at 257. R.M. had undergone plasmapheresis for three days, that "may have improved his sensory level." *Id.* The impression remained transverse myelitis. *Id.* at 259.

#### **b. Ms. Brenlee McBane's Affidavit**

Petitioner filed an affidavit from Ms. Brenlee McBane, R.M.'s mother to describe the events after R.M. received the vaccines at issue. Pet'r Ex. 15. She stated that she took R.M. to the Rose City Urgent Care and Family Practice on March 9, 2016, where he received the ProQuad vaccine in his right arm and the Kinrix vaccine in his left arm. *Id.* ¶ 3. R.M. fell asleep in the car and woke up from his nap with a fever of 103 degrees. *Id.* at ¶ 4. Ms. McBane called the doctor and he indicated that it was normal for a fever to occur after the vaccination, but if it got worse to return to the office. *Id.*

According to Mrs. McBane, R.M. had a runny nose, cough, and breathing problems, and threw up in the "following days." *Id.* at ¶ 5. R.M. had a fever that would "come and go." *Id.* R.M.'s symptoms began to go away three weeks later, although Mrs. McBane stated that R.M. "was not able to speak very well," and that she and her husband were having a hard time understanding what he was saying. *Id.* at ¶ 6.

In May, the family took a trip to Detroit Lake for a fishing derby. *Id.* at ¶ 7. Throughout the trip, R.M. did not want to keep his shoes on. One day, we went to the lake and there were rocks there. R.M. began walking on the rocks. He did not seem to be in any discomfort or pain as he walked across them. Pet'r Ex. 15 at ¶ 7. She stated, "The following day, we went to 7/11. Normally, when we went to 7/11, R.M. would run up the steps as quickly as he could. This time he did not even want to walk. I had to carry him all the way up the stairs and around in the store." *Id.* ¶ 8.

Mrs. McBane stated, "That night, we were at home and R.M. was laying on his back in bed watching a video. I took the video from him and he could not get up to chase me to try to

get the video back. He began to scream and cry because his legs began to hurt him. He seemed to be losing sensation in his legs. It was then I realized that he may be paralyzed. Anytime that he would try to walk he would continuously scream and cry.” *Id.* at ¶ 9.

### c. Petitioner’s expert reports

Dr. Martinez-Arizala wrote that common causes of transverse myelitis, such as a vitamin B12 deficiency, rheumatological disorders, neoplasms, Lyme disease, and viral infections, were excluded with comprehensive laboratory tests and neuroimaging studies. *Id.* at 6. He stated that “In R.M.’s case, [the] transverse myelitis was caused by his vaccination,” and that “Systemic infections or immunizations precede many cases of transverse myelitis. Vaccines are a well-recognized trigger factor for transverse myelitis, and this has been consistently reported in the literature.” *Id.* Dr. Martinez-Arizala proposed a theory of molecular mimicry and stated that “components of the vaccine possess sequence similarities between it and specific human proteins that results in the cross-reactivity of autoreactive T or B cells. This immune cross reactivity, causes a reaction of the immune system against the pathogenic antigens that may harm the similar human proteins, essentially causing autoimmune disease.” *Id.* at 8.

He noted that “multiple cases of post-vaccination TM have been reported in the literature.” *Id.* Dr. Martinez-Arizala, referencing Agmon-Levin et al., wrote that “[thirty-seven] cases of transverse myelitis occurred after vaccinations, which included six cases associated with the MMR vaccine and four associated with the DPT or DT vaccines. In most of these cases, the temporal association was between several days and three months, although a longer time frame was also suggested.” *Id.*; *see also* Pet’r Ex. 26.<sup>3</sup> He noted that the article by Chandra et al. reported a case of transverse myelitis where symptoms started ten days after vaccinations for MMR and influenza. *Id.* Dr. Martinez-Arizala wrote that R.M.’s symptoms began “seven weeks after the vaccinations,” that this onset was “quite consistent with the literature as noted above.” *Id.* at 7.

In response to the Rule 5 Order and Order to Show Cause, where I noted that the onset of R.M.’s symptoms appeared to be closer to 67 days post-vaccination, Dr. Martinez-Arizala wrote that “the time interval of 67 days from vaccination to the onset of symptoms is longer than ordinary, but it is not unusual.” Pet’r Ex. 43 at 1. He again cited to the Agmon-Levin study and wrote that the authors found “several cases with equally long, or longer-time intervals.” *Id.* He then referenced a case report by Bir et al., where the onset of transverse myelitis occurred two months after a 25-year-old man received a rabies vaccination. *Id.*; Pet’r Ex. 45 at 1.<sup>4</sup> He also referenced Karaali-Savrun et al. and Shaw et al., two articles that described case reports of transverse myelitis after administration of the hepatitis B vaccine, where timing of onset of

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<sup>3</sup> N. Agmon-Levin et al., *Transverse Myelitis and Vaccines: A multi-analysis*, 18 *Lupus* 1198-1204 (2009). [Pet’r Ex. 26].

<sup>4</sup> Bir, Levent Sinan, et al., *Acute Transverse Myelitis at the Conus Medullaris Level After Rabies Vaccination in a Patient with Behcet’s Disease*, 30 *J. Spinal Cord Med.* 294-96 (2007). [Pet’r Ex. 45].

transverse myelitis symptoms ranged from six weeks to sixteen weeks post-vaccination. *See* Pet'r Exs. 46<sup>5</sup> & 47.<sup>6</sup>

#### **d. Respondent's expert report**

Respondent submitted an expert report from Dr. Timothy Lotze, a pediatric neurologist. Resp. Ex. A. Dr. Lotze agreed that R.M. had transverse myelitis. *Id.* at 7. He opined that "there is no relationship between R.M.'s diagnosis of acute transverse myelitis and the vaccinations given 9 weeks and 6 days before his first symptom." *Id.*

Dr. Lotze wrote that "he agreed with Dr. Martinez-Arizala that R.M. first developed neurological symptoms through the evening of 5/16/2016 into 5/17/2016, but I disagree that this was 7 weeks from the time of his vaccinations on March 9, 2016. The difference in time between the dates is 9 weeks and 6 days, which is well outside the window to consider any relationship between the vaccines and his disease." *Id.* Dr. Lotze noted that the case reports cited by the Agmon-Levin paper, such as the case reported by Label and Batts, appeared to have discrepancies between the timeline between vaccination and onset of transverse myelitis symptoms. *Id.* at 5. He asserted that the case report from the Label and Batts article, which described the development of transverse myelitis after a man received the rabies vaccine demonstrated a seven-day timeline between the final vaccination and the onset of transverse myelitis symptoms. *Id.* The Label and Batts paper wrote that a 50-year old man received a rabies vaccine on October 10<sup>th</sup>, after being bitten by a racoon. Resp. Ex. A, Tab 3.<sup>7</sup> On the fourth day of the treatment, the man began to develop fatigue, lethargy, and "strange sensations" in his head. *Id.* Two-days prior to coming into the emergency department on October 22<sup>nd</sup>, the patient began to experience neck stiffness, numbness and weakness in his lower extremities. *Id.* He was diagnosed with transverse myelitis and treated with steroids. *Id.* Dr. Lotze stated that the case report indicates a seven-day onset between the vaccinations and symptoms of transverse myelitis. Resp. Ex. A at 5. Dr. Lotze indicated that first symptoms of transverse myelitis were numbness, weakness and neck stiffness, which began on October 20<sup>th</sup>, seven days after the administration of the last vaccine, while Agmon-Levin appears to consider the fatigue, lethargy and "strange sensations" as the first symptoms of onset, which would put them at two-days post- vaccination.

Dr. Lotze also wrote that the Institute of Medicine ("IOM") performed a comprehensive review of the medical literature literature of vaccine-related transverse myelitis and "reached the conclusion that the epidemiologic and mechanistic evidence is insufficient or absent to find an association between [Dtap and MMR] vaccines and transverse myelitis." *Id.* at 6; *see also* Resp. Ex. A, Tab 7. He opined that any incidents of transverse myelitis and vaccinations "is

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<sup>5</sup> F. Karaali-Savrun et al., *Hepatitis B vaccine-related myelitis?* 8 European J of Neurol. 711-15 (2001). [Pet'r Ex. 46].

<sup>6</sup> F.E. Shaw et al., *Postmarketing Surveillance for the Neurologic Adverse Events Reported After Hepatitis B Vaccination*, 127 American J. of Epidemiology 337-352. [Pet'r Ex. 47].

<sup>7</sup> L. Label, et al., *Transverse Myelitis Caused by Duck Embryo Rabies Vaccine*, 39 Arch. Neurol. 426-30 (1982). [Resp. Ex. A, Tab 3].



coincidental and does not equate to causation.” *Id.* Dr. Lotze concluded his report by reiterating his opinion that the vaccinations were the not the cause of R.M.’s transverse myelitis.

### III. Standard for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. §10(a). To receive compensation through the Program, petitioner must prove either (1) that he suffered a “Table Injury”—i.e. an injury listed on the Vaccine Injury Table—corresponding to a vaccine he received, or (2) that he suffered an injury that was actually caused by a vaccination. *See* §§11(c)(1), 13(a)(1)(A); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006).

Because petitioner does not allege that R.M. suffered a Table Injury, he must prove a vaccine that R.M. received actually caused his injury. To do so, petitioner must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378-49 (Fed. Cir. 2009). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, and treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). The third *Althen* prong requires establishing a “proximate temporal relationship” between vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorders etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause the injury (*Althen* prong one requirement). *Id.* at 1352. Evidence demonstrating petitioner’s injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the ‘but-for’ prong of the causation analysis. *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1358 (Fed. Cir. 2006).

Petitioner cannot establish entitlement to compensation based solely on assertions. Rather a vaccine claim must be supported by either medical records or by the opinion of a medical doctor. § 13(a)(1). The special master is required to consider “all relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature,

causation, and aggravation of the petitioner's illness, disability, injury, condition, or death" as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." §13(b)(1)(A). Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378 (fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No.11-685V, 2013 WL 1880825, at \*3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)), *mot. for rev. denied*, 142 Fed. Cl. 247 (2019), *vacated on other grounds & remanded*, 809 F.App'x 843 (Fed. Cir. 2020).

#### IV. Analysis and Conclusion

The ultimate matter in this case is not the theory of vaccine causation proposed by petitioner's expert, Dr. Martinez-Arizala, but the theory proposed in connection with the onset of R.M.'s transverse myelitis. The third prong of *Althen* requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *ALthen*, 418 F.3d at 1281. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe, which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation. *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury. *Id.*; *see also Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

Dr. Martinez-Arizala opined that the vaccine R.M. received on March 9, 2016 could result in transverse myelitis through a theory of molecular mimicry. Pet'r Ex. 16 at 6. He noted that medical literature, including the articles by Rojas and Agmon-Levin endorse a theory of molecular mimicry as a mechanism for inducing an autoimmune disease, such as transverse myelitis. *See* Pet'r Exs. 24<sup>8</sup> and 44. The theory of molecular mimicry has been accepted as a causal mechanism for inducing transverse myelitis and other central nervous system diseases in this program and I have accepted such a theory in other cases. *See e.g. Le v. Sec'y of Health & Human Servs.*, No. 16-1078V, 2023 WL 3049203 (Spec. Mstr. Fed. Cl. Mar. 30, 2023) (finding that the Tdap vaccine can cause transverse myelitis through the mechanism of molecular mimicry); *Roberts v. Sec'y of Health & Human Servs.*, No. 90-427V, 2013 WL 5314698, at \*6-7 (Fed. Cl. Spec. Mstr. Aug. 29, 2013) (finding the petitioner entitled to compensation in a Tdap/TM case with the theory of molecular mimicry); *Introiini v. Sec'y of Health & Human Servs.*, No. 20-176V, 2022 WL 16915818 (Fed. Cl. Spec. Mstr. Oct. 19, 2022) (finding that the Tdap vaccine can cause TM via molecular mimicry); *White v. Sec'y of Health & Human Servs.*,

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<sup>8</sup> M. Rojas et al., *Molecular mimicry and autoimmunity*, 95 J. of Autoimmunity 100-23. [Pet'r Ex. 24].



No. 15-1512V, 2019 WL 7563239 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (finding that the HPV vaccine can cause transverse myelitis through a theory of molecular mimicry). Thus, I am willing to accept petitioner's theory of molecular mimicry as a causal mechanism for transverse myelitis.

Dr. Martinez-Arizala opined that a 67-or-68-day timeframe after vaccination is a medically acceptable timeframe for transverse myelitis symptoms to begin to infer causation. Pet'r Ex. 16 at 7; Pet'r Ex. 43. The case reports he references in his second report, where onset of transverse myelitis occurred six to seven weeks post-vaccination, are not persuasive. In particular because these case reports are referencing the onset of transverse myelitis after administration of the hepatitis B vaccine, which is not at issue in this matter. *See* Pet'r Ex. 46 (describing four cases of transverse myelitis after administration of the hepatitis B vaccine). The Agmon-Levin article, which includes a more comprehensive review of transverse myelitis following vaccination, notes that four cases of transverse myelitis were identified following receipt of the measles-mumps-rubella or rubella vaccines, but onset began at the earliest four days post-vaccination and the latest, 21 days post-vaccination. *See* Pet'r Ex. 44. Of the DTP, DT or pertussis vaccines reported Agmon-Levin, the intervals between vaccination and onset of symptoms was between three and seventeen days. *Id.* In another case report referenced by Dr. Martinez-Arizala, onset of neurological symptoms of transverse myelitis occurred ten days after administration of the influenza and MMR vaccines. Pet'r Ex. 29.<sup>9</sup> Two additional case reports were listed in the Journal of Paediatrics & Child Health Letter to the Editor, describing the onset of transverse myelitis in a 14-year-old girl eight days after receiving the diphtheria-tetanus, oral polio, and rubella vaccines and a young boy developing transverse myelitis twenty-three days after receiving the diphtheria-tetanus toxoid and oral polio vaccines. Pet'r Ex. 30 at 1.<sup>10</sup> The medical literature filed in this case, puts the onset of transverse myelitis much closer in time to vaccination, compared to the interval between R.M.'s vaccines and his transverse myelitis.

R.M. received the diphtheria-tetanus-acellular-pertussis and inactivated polio vaccine and the measles, mumps, rubella, and varicella vaccine on March 9, 2016. There are no medical records between the time of vaccination and May 16, 2016, when he initially presented to the emergency department of St. Vincent Medical Center for an evaluation of leg pain and being unable to walk. Pet'r Ex. 3 at 2. The medical record from Oregon Health & Science University pediatric neurology consult provides more detail as to when R.M. was last seen walking, which was earlier in the day on May 16, 2016. It explains:

[R.M.] is a 4-year 3 month previously healthy male with acute onset lower extremity paraplegia. Was in his usual state of health until Monday evening. Mom walked with [R.M.] to get a slurpee at 7-11 around 6:30 pm. He was walking fine. Went home and he was laying on mom's bed playing with her phone. She took her phone away to answer the phone and he started whining and slid off the bed....Mom picked him up and put him back on the bed...She then left the room and then when went back into the room he was on the floor again. She did not see if he fell or if he tried to walk and fell. Seemed to be

<sup>9</sup> A.Chandra et al., *Vaccine Induced Acute Transverse Myelitis: A Case Report*, 13 Nepal J. of Neuroscience 89-91 (2016). [Pet'r Ex. 29].

<sup>10</sup> *Letter to the Editor*, 41 J. Paediatr. Child Health 460 (2005). [Pet'r Ex. 30].

clutching at his lower abdomen/suprapubic area. When he was crying for 30 minutes, mom took him to ED at St. Vincent. While he was there he complained of abdominal pain. Was discharged. However, worsening pain so returned to DCH ED. Was evaluated for abdominal pain, but when [R.M.]...stood up to be discharged noted to have paralysis.

Pet'r Ex. 2 at 26. This record is also consistent with what the emergency department physician, Dr. Cloutier wrote when R.M. was taken back into the emergency department after throwing up again in the car. He wrote, "Patient refused to stand and appeared to have flaccid paralysis below the hips. Upon further interview, I learned the last time the mother had actually seen the patient walking was approximately 6:30 yesterday evening." *Id.* at 145.

As discussed in the Order to Show Cause, Ms. McBane's affidavit appears to somewhat contradict the medical record, indicating that R.M. did not walk to 7-11, but instead she had to carry him. Pet'r Ex. 15 at ¶¶ 7-8. But more significantly, Ms. McBane's affidavit does not contain a date more specific than "May" for the fishing trip or the visit to 7-11, but the medical records appear clear that the latter occurred on May 16<sup>th</sup>, prior to taking her taking R.M. to the emergency room. She describes this as the day following the fishing trip. *Id.* at ¶ 8. Further, her affidavit was created in 2022, when the medical records were contemporaneously created for the treatment of R.M. when he presented with rather dramatic symptoms. Given that the medical records appear to be internally consistent and were created contemporaneously to treat R.M. when he presented with dramatic symptoms, these records are afforded substantial weight.

Special masters have found that a petitioner was entitled to causation where onset occurred up to two months, or 56 days following the flu vaccination. *Spayde v. Sec'y of Health & Human Servs.*, No. 16-1499V, 2021 WL 686682 (Fed. Cl. Spec. Mstr. Jan. 27, 2021) (accepting a 56-day onset for GBS following flu vaccination) (citing to *Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at \*13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (finding a six-week or 42-day interval from vaccination to onset of petitioner's GBS). However, these are cases involving the influenza vaccine and Guillain-Barré syndrome, and not the occurrence of transverse myelitis following a Tdap vaccine. Further, other compensated cases where petitioners suffered from transverse myelitis following the Tdap vaccination had onset of symptoms much closer in time to the administration of the vaccine. *See e.g. Roberts v. Sec'y of Health & Human Servs.*, No. 09-427V, 2013 WL 5314698 (onset of symptoms began four weeks after Tdap vaccination); *Helman v. Sec'y of Health & Human Servs.*, No. 10-813V, 2012 WL 1607142, at \*3 (Fed. Cl. Spec. Mstr. Apr. 5, 2012) (finding onset of symptoms occurring three weeks after Tdap vaccination); *Raymo v. Sec'y of Health & Human Servs.*, NO. 11-0654V, 2014 WL 1092274, at \*19 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) (finding a three to four-day onset of transverse myelitis following administration of Tdap vaccine to medically appropriate temporal relationship).

As I indicated in the Rule 5 Order in this matter and in *Archer*, another late onset transverse myelitis case, I do not consider there to be hard line for establishing a medically appropriate timeframe, especially if the proposed timeframe is supported by medical literature and coincides with a sound and reliable mechanism for vaccine causation. *See Archer v. Sec'y of Health & Human Servs.*, 2021 WL 2666692, at \*24 (Fed. Cl. Spec. Mstr. May 27, 2021).

However, in this matter, the medical literature Dr. Martinez-Arizala referenced to support an onset of 67 days post-vaccination refers to a vaccine that R.M. did not receive on March 9, 2016, and the range for symptom onset post-vaccinations regarding the vaccines that R.M. did receive was much closer in time that in this matter. Accordingly, petitioner did not provide preponderant evidence to satisfy *Althen* prong three.

## **V. Conclusion**

It is not without difficulty that I have come to the conclusion discussed above, as R.M. clearly has a permanent, disabling condition. Unfortunately, the evidence that was submitted in this matter, including the medical literature, the medical records, and the expert reports, is insufficient to demonstrate that the vaccines R.M. received on March 9, 2016, played a causal role in him developing transverse myelitis 67 days post-vaccination.

Accordingly, petitioner's claim must be and is hereby **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court is directed to enter judgment forthwith.<sup>11</sup>

**IT IS SO ORDERED.**

**s/ Thomas L. Gowen**

Thomas L. Gowen  
Special Master

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<sup>11</sup> Entry of judgment is expedited by each party's filing notice renouncing the right to seek review. Vaccine Rule 11(a).